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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,517	07/09/2001	J. Jeffrey Seilhamer	219002025213	7422

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EXAMINER	
EPPS, JANET L	

ART UNIT	PAPER NUMBER
1635	16

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/902,517	Applicant(s) SEILHAMER ET AL.	
	Examiner Janet L. Epps-Ford, Ph.D.	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32 and 41-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32 and 41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 32 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sudoh et al. in view of Hirth et al.

Claim 32 is drawn to antibodies useful for immunoassays to detect a peptide which peptide comprises human brain natriuretic peptide of the formula: Ser-Pro-Lys-Met-Val-Gln-Gly-Ser-Gly-Cys-Phe-Gly-Arg-Lys-Met-Asp-Arg-Ile-Ser-Ser-Ser-Ser-Gly-Leu-Gly-Cys-Lys-Val-Leu-Arg-Arg-His, or a C-terminal amide thereof.; Claims 41-44 are drawn to the antibodies of claim 32, wherein said antibodies are monoclonal, further comprise a label, methods to perform an immunoassay comprise the use of the antibodies of claim 32, and a kit for conducting an immunoassay.

Sudoh et al. disclose antibodies and their use thereof in an immunoassay to identify the presence of atrial natriuretic peptide (ANP) in mammalian tissue. Sudoh et al. teach the identification of "ANP-like" immunoreactivity present in brain extracts from porcine brain tissue (see Figure 1). Identifying fractions with "ANP-like" immunoreactivity (using anti-rat ANP) and further testing of these fractions for relaxant activity allowed Sudoh et al. to further characterize the "ANP-like" activity of these fractions (see Figure 1a). Further purification of fractions with "ANP-like" activity allowed for the identification of a new natriuretic peptide in porcine brain

(pBNP). Additionally, Sudoh et al. disclose the amino acid sequence of porcine brain natriuretic peptide (See Figure 2b). Sudoh et al. implicate pBNP in the regulation of physiological functions such as water intake and salt appetite (see page 80, 2nd paragraph). Additionally, Sudoh et al. speculates that it is probable that BNP is also present in other organs, such as heart, wherein it may function in concert with ANP to maintain the homeostatic balance of body fluid (see page 80, 3rd paragraph).

However, Sudoh et al. does not disclose antibodies or monoclonal antibodies that are specifically useful for detecting a peptide that comprises human brain natriuretic peptide, kits comprising said antibodies, or methods to perform an immunoassay to detect human or canine natriuretic protein in a sample.

Hirth et al. disclose methods for isolating antibodies directed to the atrial natriuretic peptide, wherein the antibodies can be used, for example, for the determination of the levels of ANPs in biological fluids, isolating ANPs using chromatography, and for immunoassays (see col. 2, lines 51-59). Hirth provides methods also for the preparation of monoclonal antibodies against atrial, natriuretic peptides of humans and rats, see Example 1 (col. 4-5).

It would have been obvious to one of ordinary skill in the art at the time of filing to modify the teachings of Sudoh et al. with the teachings Hirth et al. in the isolation of antibodies, and monoclonal antibodies targeting BNP, kits comprising said antibodies, and methods for performing an immunoassay using these antibodies. One of ordinary skill in the art at the time of filing would have been motivated to make this modification since Sudoh et al. clearly expresses a clear desire to further elucidate the expression pattern of BNP in other tissues, for example the heart, and to further characterize it's role in maintaining the homeostatic balance of body fluid.

Furthermore, Hirth et al. clearly provides a means for isolating antibodies, in particular monoclonal antibodies, against a natriuretic peptide, and its use for characterizing a natriuretic peptide in body fluids and in immunoassays. Although, Sudoh et al. does not disclose human BNP, absent evidence to the contrary one having ordinary skill in the art would have expected at the time of filing that antibodies targeting porcine BNP would share some sequence homology to human BNP and would likely have cross reactivity with human BNP.

Therefore the invention as a whole would have been *prima facie* obvious over Sudoh et al. in view of Hirth et al.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
March 20, 2003

SEAN McGARRY
PRIMARY EXAMINER